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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,464	02/17/2004	Srinivasa Madhyastha	14233.15USU1	1780
23552	7590	03/01/2007	EXAMINER	
MERCHANT & GOULD PC			KAM, CHIH MIN	
P.O. BOX 2903			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55402-0903			1656	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	03/01/2007		PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,464 Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 December 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 42-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 42-53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 September 2005 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Status of the Claims

1. Claims 42-53 are pending.

Applicant's amendment filed December 11, 2006 is acknowledged, and applicants' response has been fully considered. New claims 47-53 have been added. Therefore, claims 42-53 are examined.

Withdrawn-Claim Rejections - 35 U.S.C. § 103

2. The previous rejection of claims 42-46 under 35 U.S.C. § 103(a) as being unpatentable over Willcox *et al.* (CA 2, 284,364) taken with Tomita *et al.* (EP 629347) and Johansen (WO 96/06532), is withdrawn in view of applicant's response at pages 4-8 in the amendment filed December 11, 2006.

Maintained Claim Objections

3. Claim 43 is objected to because of the use of the term "a voice prosthetic". The claim is also objected to because it recites "tubing" twice. Applicants indicates claim 43 has been amended to correct the terms of "a voice prosthetic" and "tubing". However, claim 43 has not been amended, thus the objection is maintained.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 42-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 42-53 are directed to a medical device comprising a composition for inhibiting a bacterial biofilm, the composition comprising (a) ovotransferrin, protamine sulfate and EDTA or (b) ovotransferrin and protamine sulfate; or an article for inhibiting a bacterial biofilm comprising a coating and a device wherein said coating comprises: (a) ovotransferrin, protamine sulfate and EDTA or (b) ovotransferrin and protamine sulfate. While the specification indicates the present invention provides a composition comprising (a) a small amount of at least one iron-sequestering glycoprotein such as ovotransferrin; (b) a sparing amount of at least one cationic polypeptide such as protamine sulfate; and (c) a sparing amount of at least one chelating agent such as EDTA, wherein the amount of each of components (a) and (b), or, components (a), (b) and (c) is sufficient to form, in combination, a synergistic, antimicrobial composition; the iron-sequestering glycoprotein is between about 125 mg/L and 2000 mg/L, the cationic polypeptide is between about 12.5 mg/L and 200 mg/L and the chelating agent is between about 12.5 mg/L and 200 mg/L; and the invention also discloses preparing a medical device by treating a surface of the device with the composition having specific amount of ovotransferrin, protamine sulfate and EDTA that inhibits bacterial biofilm (paragraphs [0011]-[0019]), the specification does not describe any amount of each of components (a) and (b), or, components (a), (b) and (c) is sufficient to form, in combination, a synergistic, antimicrobial composition. The use of each component (i.e., ovotransferrin, protamine sulfate and EDTA) in a specific range (paragraph [0015]) in the synergistic, antimicrobial composition for coating medical device (i.e. Examples

1-5) does not provide the original written description for a genus of variants of compositions comprising any amount of ovotransferrin, protamine sulfate and EDTA that would inhibit bacterial biofilm. Without guidance on the use of various amounts of each component in the composition, one skilled in the art would not know whether a composition with any amount of each component would produce a synergistic, antimicrobial effect and would inhibit bacterial biofilm on the device. The lack of description on the use of a composition comprising various amounts of each component in coating the device and lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK
February 27, 2007